

- Visegrad Fund



Organizational support in clinical trials in Slovakia

Daniela Svetlovska

Department of Clinical Trials, National Cancer Institute

Bratislava, Slovakia

Oncology diseases

Cancer is a leading cause of death worldwide

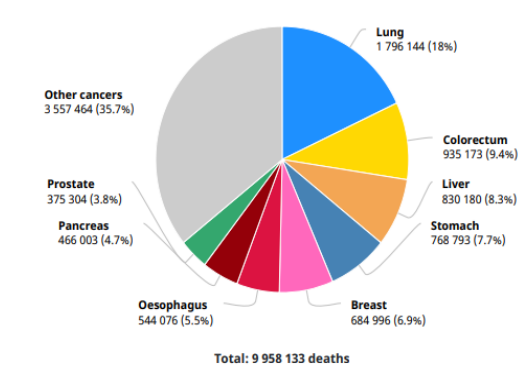
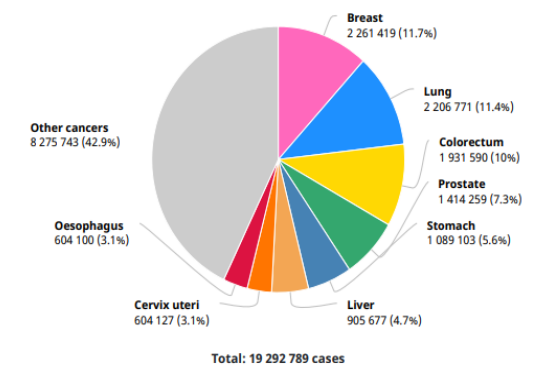
International Agency for Research on Cancer
World Health Organization

All cancers

Source: Globocan 2020

Number of new cases in 2020, both sexes, all ages

Number of deaths in 2020, both sexes, all ages



Cancer incidence and mortality statistics worldwide and by region

	Incidence						Mortality					
	Both sexes		Males		Females		Both sexes		Males		Females	
	New cases	Cum. risk 0-74 (%)	New cases	Cum. risk 0-74 (%)	New cases	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)
Eastern Africa	331 233	13.56	126 826	11.90	204 407	15.12	222 189	9.91	88 039	8.71	134 150	11.02
Middle Africa	106 467	11.68	45 718	11.71	60 749	11.83	71 570	8.35	31 814	8.25	39 756	8.54
Northern Africa	307 507	14.61	148 423	15.14	159 084	14.16	191 081	9.21	103 915	10.43	87 166	8.05
Southern Africa	116 391	20.00	54 358	22.74	62 033	18.22	61 659	11.50	29 578	13.38	32 081	10.22
Western Africa	247 611	11.69	100 428	10.67	147 183	12.71	164 930	8.44	70 537	7.89	94 393	8.99
Caribbean	113 280	19.72	59 679	22.35	53 601	17.42	65 954	10.44	36 290	11.83	29 664	9.23
Central America	261 646	14.30	120 657	14.71	140 989	14.01	126 071	6.91	61 544	7.15	64 527	6.72
South America	1 095 348	20.24	539 931	22.09	555 417	18.79	521 389	9.45	267 301	10.59	254 088	8.51
Northern America	2 556 862	33.93	1 372 002	37.05	1 184 860	31.09	699 274	9.22	367 856	10.31	331 418	8.23
Eastern Asia	6 008 355	21.91	3 295 730	24.58	2 712 625	19.37	3 617 104	13.10	2 174 803	16.35	1 442 301	9.87
South-Eastern Asia	1 100 037	15.62	526 190	16.46	573 847	15.03	689 093	10.08	373 795	11.82	315 298	8.55
South-Central Asia	1 951 843	10.93	966 677	11.13	985 166	10.78	1 258 683	7.41	660 359	7.88	598 324	6.95

Unmet need

- more efficient treatment
- more tolerable drugs
- to improve patient's quality of life



Research is needed

Oncology clinical trials-specific

Extremely difficult

- High frequency of adverse events and serious adverse events
- Many concomitant medications taken
- Treatment until progression
- Many versions of informed consents during the study
- Studies last for years (overall survival, progression survival)

Support is needed



Quality of research is required



AUDITS, INSPECTIONS



Department of Clinical Trials

Organizational

Administrative

Consultation

support

Clinical trials in NCI Slovakia

- Academic research (testicular, breast cancer, probiotics)
- International non-commercial (EORTC, CECOG)
- Industry sponsored trials

Department of Clinical Trials -National Cancer Institute (NCI) Slovakia

- Department of Clinical Pharmacology

Jozef Hal'ko, MD, RNDr.

(participated in creation of laws in Slovakia, Health authority)

PharmDr. Eva Chalachanová
1st Head of Department of Clinical Trials



1995 Department of Clinical Trials
Ass.prof. Štefan Korec, MD, PhD
(fellowship in USA, Head of NCI 1995)



NCI Slovakia Academic clinical trials

Clinical Trials in Testicular Germ Cell Cancer and Breast Cancer in National Cancer Institute in Slovakia

1990 - 2022

TGCC

- 1) Sequential intermediate high-dose therapy with etoposide, ifosfamide and cisplatin for patients with GCTs. A Phase II study. J. Mardiak.
- 2) Carboplatin and cyclophosphamide in the treatment of metastatic seminoma. A Phase II study. J. Mardiak.
- 3) Gemcitabine plus cisplatin and paclitaxel (GCP) in second-line treatment of GCTs. A Phase II study. J. Mardiak.
- 4) Paclitaxel plus ifosfamide and cisplatin in second-line treatment of GCTs: A phase II study. J. Mardiak.
- 5) Paclitaxel, bleomycin, etoposide, and cisplatin (T-BEP) as initial treatment in patients with poor-prognosis GCTs: A Phase II study. J. Mardiak.
- 6) Bevacizumab in a growing teratoma syndrome. Case report. J. Mardiak.
- 7) 18031977 The histone deacetylase inhibitor (HDAC) valproic acid as second line treatment for hormone refractory metastatic prostate cancer. A phase II. Study. M. Mego

8) GCTSK 001 - Phase II study of Sunitinib in refractory TGCTs. J. Mardiak., M. Rečková

9) GCTSK 002 - Phase II study of Everolimus refractory TGCTs. J. Mardiak., M. Mego.

10) GCTSK 003 - First Line TIP in Poor Prognosis TGCTs . J. Mardiak., M. Mego.

11) GCTSK 004 - Phase II study, Study of Gemcitabine, Carboplatin and Veliparib in refractory TGCTs . J. Mardiak., M. Mego.

12) GCTSK 005 - Phase II study of Avelumab refractory TGCTs. M. Mego

13) GCTSK 006 - Phase II study of Disulfiram and cisplatin in refractory TGCTs. M. Mego

Breast Cancer

- 1) Adjuvant clodronate therapy in patients with locally advanced breast cancer--long term results of a double blind randomized trial. Slovak Clodronate Collaborative Group. J. Mardiak
- 2) BREAST-SK-001 Phase II study of Vinorelbine, cisplatin, disulfiram and copper in CTC_EMT positive refractory metastatic breast cancer. M.Mego

EORTC (European organization of research and treatment of cancer)

- International protocol for EORTC-62972 written by investigator -
Dr. L. Švancárová
- International meetings for Sarcoma group in NCI Slovakia
- Also active in Lymphoma, Genito-urinary and Infectious diseases groups

Results

- 1456 patients in interventional studies phase I-IV (2000-2022)
- **235 interventional studies phase I-IV (2003-2022)**

Sytemic organization

- Input and 25 years NCI Slovakia experiences (M. Mego, L. Drgoňa, D. Světlovská and team A. Jančíková, A. Krieschová, S. Turňová)
- Ministry of Health (I. Kvietiková, S. Špánik)
- Support from Health Authority (K. Kováčová)
- National Oncology Institute (M. Rečková)
- Slovacin (B. Čečetková)

Minister's order in SR 4/2018

- Add into hospital organization structure **Departments (of Clinical Trials and Biomedical research departments)**
- **voluntary for hospitals**

Minister's order in SR 4/2018

- Defined job description and duties
- Minimal defined positions for departments-study coordinator, study nurse
- Speeding up the process of concluding contracts (to reply to maximum to 30 days)
- Subordinated to medical director

b) začleniť do organizačného poriadku organizačný útvar – referát, odbor alebo oddelenie klinického skúšania (ďalej ako „organizačný útvar“⁴) s nasledovnou pôsobnosťou:

Bratislava 10. októbra 2018
Číslo: S11828-2018-OVV-0001

Príkaz ministerky zdravotníctva SR
č. 4/2018

Za účelom skvalitnenia biomedicínskeho výskumu a klinického skúšania humánnych produktov a humánnych liekov

prikazujem
s účinnosťou od 15. novembra 2018

Článok I.

Štatutárnym orgánom

- *štátnych príspevkových organizácií v pôsobnosti ministerstva,*
- *akciových spoločností, v ktorých je ministerstvo akcionárom*
(ďalej spoločne ako „podriadené organizácie“)

After 3 month....

- 12 new Departments of Clinical Trials
- 7 new Departments of Biomedical Research



D. Světlovská, L. Drgoňa, M. Mego, P. Čvapek, D. Kollár, K. Kováčová, R. Imrich, B. Čečetková, P. Valkovič, J. Rosocha, S. Špánik, I. Kvietiková

https://www.nou.sk/sites/default/files/stranky/2019-09-zdn32_2019_07_2_ks_biomedicinsky_vyskum.pdf

Systémová podpora klinického... nou.sk

Súbor Úpravy Prejť na Obrúbené položky Pomocník

Zdravotnícke noviny **ODBORNÉ FÓRUM** 7

Príkaz MZ č. 4/2018

Organizačná podpora klinického skúšania a biomedicínskeho výskumu v SR

Na Slovensku sa definovala a zjednotila infraštruktúra na zlepšenie podmienok vykonávania výskumu



Foto: archív

Literatúra:
¹ Saxon EA, Boren SA. Managing clinical knowledge for health care improvement. In: Benmueli, McCray AT, editors. Yearbook of Medical Informatics 2000: Patient-Centered Systems. Stuttgart, Germany: Schattauer Verlagsgesellschaft mbH; 2000:65-70.
² Institute of Medicine (US) Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule. Nass SJ, Levit LA, Gostin LO, editors. Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research. Washington (DC): National Academies Press (US); 2009. 3. The Value, Importance, and Oversight of Health Research. Available from: https://www.ncbi.nlm.nih.gov/books/NBK9571/ Hatfield M, Sommerschein HF, Rosenberg LE. Exceptional returns: The economic value of America's investment in medical research. 2001. [accessed August 21, 2008].
³ https://www.stkl.sk/Bonus/ktoc/Klinicke_skusanie_liekov/Pojmov_Definicie_najdolezitejsich_pojmov_45_3_2_2013.pdf
⁴ Zákon o lieku 362/ 82Z (1), definície
⁵ https://www.royalsmarden.nhs.uk/about-us/our-research/clinical-trials, 25.6.2019
⁶ http://www.mou.cz/ztz/oddeleni-klinicky-hodnoteni/department...

TABUĽKA 1: TYPY ORGANIZAČNÝCH ÚTVAROV V RAMCI KLINICKEHO VÝSKUMU

Typ organizačného útvaru	Príkaz 4/2018	Príkaz 4/2018
Referent	3	3
Oddelenie	1	3
Oddor	0	1

TABUĽKA 2: TYPY ORGANIZAČNÝCH ÚTVAROV V RAMCI BIOMEDICÍNSKEHO VÝSKUMU

Typ organizačného útvaru	Príkaz 4/2018	Príkaz 4/2018
Referent	2	6
Oddelenie	3	5
Oddor	1	2

Kvalita zdravotnej starostlivosti spočíva, okrem iných faktorov, aj na výsledkoch biomedicínskeho výskumu. Biomedicínsky výskum môže viesť k dôležitým medicínskym objavom, vývoju novej diagnostiky a liečby a k zlepšeniu zdravotnej starostlivosti a verejného zdravia. Biomedicínsky výskum má tiež veľký význam z ekonomického hľadiska, keďže zvýšená produktivita populácie v SR novú zákon-

na Slovensku. Z tohto dôvodu vydalo Ministerstvo zdravotníctva SR nový zákon-

ležitý, keďže nábor v klinickom skúšaní je väčšinou kompetitívny medzi jednotlivými

Standardnou súčasťou zdravotníckych zariadení. Takisto na Slovensku sa týmto príla-

voťnicke zariadenia môžu byť významne zvýšiť počet prebiehajúcich klinických

Stahovanie (1.17 MB of 1.35 MB) : https://www.nou.sk/sites/default/files/stranky/2019-09-zdn32_2019_07_2_ks_biomedicinsky_vyskum.pdf

11:13 30.10.2019

Study coordinators

- important role in the conduction of research activities
- provides a strong support to the research team

Web survey in 115 Italian sites concluded:

direct association between the number of clinical studies and the number of coordinators

<https://doi.org/10.5301/maapoc.0000015>

Team

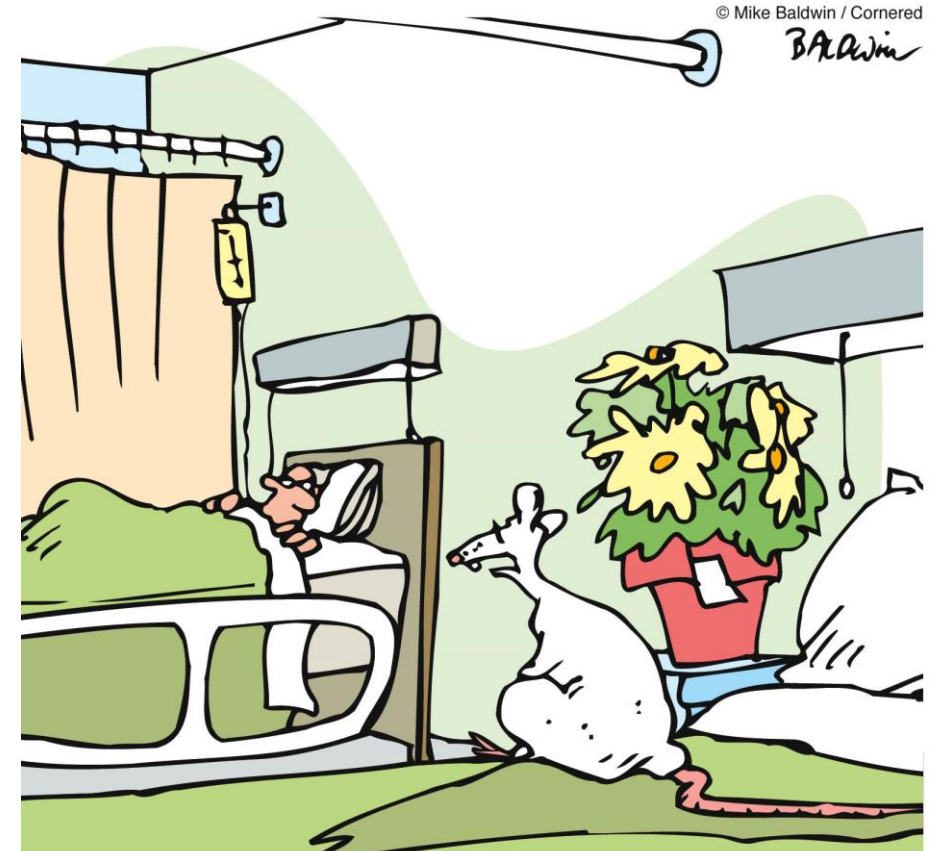


What is needed

- -catalog of professional activities
- education
- sufficient personal resources
- International collaboration

Clinical trials

- New, promising treatment
- Access to financially demanding innovative treatment for patients
- Saving public financial resources
- Accurate diagnostic and treatment criteria
- Publications and citations in peer-reviewed journals



“I go home today. They cured me using this new miracle drug. I’m afraid it’ll be years before it’s approved for humans.”

Department of Clinical Trials

- Quality of realized clinical trials
- Support to academic clinical trials
- Possibility to realize more trials
- Innovative treatment available to patients

Thank you for your attention

